

Notice of Allowability

Application No.

09/696,600

Examiner

Ashwin Mehta

Applicant(s)

PETERSON ET AL.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers filed 11 February 2005.
2. ☒ The allowed claim(s) is/are 1-10, 18, 19, 21 and 24-35.
3. ☒ The drawings filed on 21 January 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>attached</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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Priority

1. The objection to the priority statement on page 1 of the specification is withdrawn, in light of its amendment.

Claim Rejections

2. The rejection of claims 18-21, 23-25, and 34-36 under 35 U.S.C. 112, second paragraph is withdrawn in light of the claim amendments or cancellations.
3. The rejection of claims 8-10 under 35 U.S.C. 112, 1st paragraph is withdrawn in light of the claim amendments.
4. The rejection of claim 1 under 35 U.S.C. 102(a) is withdrawn in light of the claims amendments.
5. The rejection of claims 1-10 and 18-36 are rejected under 35 U.S.C. 103(a) is withdrawn in light of the declaration under 37 CFR 1.131 and the claim amendments.

Examiner's Amendment

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Heidi Nebel on April 15, 2005.

The application has been amended as follows:

In the claims,

Claim 1 A method to induce homologous recombination between nucleotide sequences having overlapping [homologous] regions within a recombination construct in a plant, wherein said recombination construct comprises a transposon flanked by said nucleotide sequences, comprising: introducing said recombination construct to the plant, and expressing a transposase within the plant to cause excision of said transposon, so as to induce homologous recombination between said nucleotide sequences within said recombination construct within said plant so that the recombined sequence encodes a protein.

Claim 5 A method to construct a functional gene in plants, comprising generating two overlapping fragments of the gene, [linking a pair of overlapping fragments with a maize Ds element,] assembling a recombination construct comprising a maize [the overlapping fragments flanking the] Ds element and the overlapping fragments flanking the Ds element in such an order that a complete sequence is obtained when these fragments are homologously recombined, introducing said recombination construct into a plant, and making available a transposase to cause excision of the Ds element, whereby homologous recombination is induced, upon excision of the Ds element, between the overlapping fragments within the recombination construct to produce a functional gene.

Claim 8 A method to control expression of a gene in a plant comprising:

- 1) generating two overlapping fragments of the gene sequence comprising regulatory elements;
- 2) linking the [a pair of] overlapping fragments with a maize Ds element;
- 3) assembling a recombination construct comprising the overlapping fragments flanking the Ds element in such an order that a complete gene sequence is obtained when these fragments are homologously recombined;
- 4) introducing said recombination construct into a plant; and
- 5) making available a transposase to cause excision of the Ds element, whereby homologous recombination is induced, following excision of the Ds element, between the overlapping fragments within the recombination construct to produce a complete gene sequence which is capable of expressing a functional transcript in plants.

Claim 18 A recombination construct comprising a DNA molecule which can be induced to undergo homologous recombination in the presence of a maize transposase, said recombination construct comprising two overlapping fragments of a gene and a maize Ds element, wherein the fragments flank the Ds element, wherein, in the presence of said transposase, the Ds element is excised and the overlapping fragments homologously recombine to form a functional gene [direct repeat sequences proximal to a Ds element and gene internal to the direct repeats].

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Claim 19 A vector comprising the [a] recombination construct of claim 18 [comprising a DNA molecule capable of undergoing homologous recombination upon introduction of a maize transposase, wherein said DNA molecule comprises direct repeat sequences proximal to a Ds element and gene internal to the direct repeats].

Claims 20, 23, and 36 were cancelled.

In claim 24, line 2, the recitation, "an agronomically significant" was replaced with the article, --a--.

In the specification,

The paragraph on page 1, under the heading "Field of the Invention", was amended as follows:

This a Continuation Application of Application Serial No. 09/208,349 filed December 9, 1998 [1 999], now abandoned. This application claims priority to Provisional Patent Application US 60/069,057 filed December 10, 1997.

7. Claims 1-10, 18, 19, 21, and 24-35 are allowed.

8. The following is an examiner's statement of reasons for allowance: Applicants have developed a method to construct a functional gene in plants, comprising assembling a

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recombination construct comprising a maize Ds element flanked by overlapping fragments of a gene. The construct is introduced into a plant. By expressing the Ac transposase, the Ds element excises from the construct, the action of which induces homologous recombination between overlapping gene fragments, resulting in a functional gene sequence. Shalev et al. (Genetics, July 1997, Vol. 146, pages 1143-1151) teach an assay for homologous recombination induced by excision of a transposable element by the maize Ac transposase in transgenic tobacco plants, resulting in recombination between two non-allelic GUS deletion fragments to yield an intact GUS gene. However, Shalev et al. do not teach the recombination of fragments present within the same recombination construct and flanking the Ds element. Swoboda et al. (EMBO, 1994, Vol. 13, pages 484-489) teach intrachromosomal homologous recombination in plants, comprising recombination between gene fragments sharing overlapping regions in a recombination construct sharing overlapping regions, and wherein a hygromycin coding sequence between the gene fragments is excised, resulting in an intact, functional GUS gene. However, Swoboda et al. did not use a transposase or other enzyme to cause excision of the hygromycin gene, or a transposon. Further, Applicants have submitted a declaration under 37 CFR 1.131 showing that the invention was conceived before the publication of Shalev et al., and shows due diligence to the time of filing and reduction to practice. Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

April 15, 2005



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Primary Examiner
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